



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/089,663 | 07/10/2002 | Armin Prasch | 3671/OK437 | 6944 |

7590 10/12/2006

Michael J Sweedler
Darby & Darby
805 Third Avenue
New York, NY 10022-7513

| |
|----------|
| EXAMINER |
|----------|

AHMED, HASAN SYED

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1615

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

74

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/089,663 | Applicant(s) PRASCH ET AL. | |
| | Examiner Hasan S. Ahmed | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 07 June 2005.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 18-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 18-34 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

U.S. Patent and Trademark Office
PTOL-326 (Rev. 08-06)

Office Action Summary

Part of Paper No./Mail Date 20060926

DETAILED ACTION

1. Receipt is acknowledged of applicants': (1) petition for extension of time; (2) Rule 132 Declaration 7 June 2005; (3) and Amendment in Response to Non-Final Office Action; all filed on 7 June 2005.
2. The 35 U.S.C. 101 rejection-of-record (Office action mail date 14 December 2004) is hereby withdrawn.
3. The 35 U.S.C. 102 rejection-of-record (Office action mail date 14 December 2004) is hereby withdrawn.
4. Applicants' arguments have been considered, but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 18-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 18-34 are drawn to a "depot" medicament formulation. According to the instant specification, "[r]elease of the active ingredient is intended with the described drug forms to take place in a delayed and gradual manner, resulting in a prolonged

Art Unit: 1615

action for these drug forms in the sense of a depot.” See page 1, lines 9-12. However, no evidence is provided in the specification that applicants have accomplished “depot” pharmacokinetics. No examples or data are provided that show a delayed or prolonged release of active agent using the medicament formulation claimed.

2. Claims 18-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, claims 18-34 are drawn to a “depot” medicament formulation. While examiner acknowledges that the term “depot” is given a broad definition in the instant specification (see page 1, lines 10-12), the term is not defined by the instant specification in a clear and concise manner as applied to the invention being claimed. As such, the disclosure of the instant specification is not sufficient to support the concept of “depot” medicament formulation, as claimed, and requires further clarification.

3. Claims 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the specification does not teach how to make a medicament formulation comprising ceramic granules or calcium phosphate. No examples are provided.

4. Claims 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the specification does not teach how to make a bone replacement implant. No examples are provided.

Art Unit: 1615

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the phrase "granule mixture of particles" is unclear. Clarification is requested.
2. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is unclear whether "mixed granules" refers to a mixture comprising (a) granules made of only plasma protein and granules made of only active ingredient, or (b) granules made of both plasma protein and active ingredient. Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-25, 28-31 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heath, et. al. (WO 97/44015).

Heath, et. al. teach a granulated fibrin tissue adhesive formulation (see col. 3, lines 28-39). The disclosed formulation is comprised of:

- the blood plasma protein of instant claim 18 (see page 2, line 35);

Art Unit: 1615

- the fluidized bed drying of instant claim 18 (see page 3, lines 19-25);
- the thrombin of instant claim 18 (see page 2, line 35);
- the carrier granules of instant claim 18 (see page 3, lines 9-18);
- the active agent of instant claim 18 (see page 2, line 35);
- the carrier system of instant claims 19-21 (see page 3, lines 9-18);
- the granule comprised of an internal core of mannitol and external layer plasma protein of instant claims 22 and 23 (see page 3, lines 32-36);
- the substance which promotes wound healing of instant claim 28 (see page 2, line 35);
- the topical, parenteral, and transdermal routes of administration of instant claims 29-31 (see Example); and
- the process of producing a depot medicament of instant claim 34 (see page 3, lines 19-25).

Heath, et. al. explain that a granulated blood plasma protein medicament formulation formed by spray-drying is beneficial because it provides, "...good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, not in the delivery system." See page 3, lines 1-7.

While Heath, et. al. do not explicitly teach the particle sizes recited in instant claims 18, 24, and 25, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable particle sizes through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in particle size will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant particle sizes.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a granulated blood plasma protein medicament formulation, as taught by Heath, et. al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a formulation because of good flow properties, enhanced, effective delivery to the active site, and dissolution only at the site, as explained by Heath, et. al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 1615

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-25, 28-31 and 34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 13 of U.S. Patent No. 6,596,318 (U.S. '318). Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. '318 claims a granulated blood plasma protein medicament formulation (see claim 1) produced by fluidized bed drying (see col. 16).

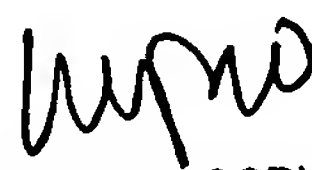
One of ordinary skill in the art at the time of the invention would have expected similar effects from the formulation of the instant claims, given the claims of U.S. '318. Thus, the instant claims for a granulated blood plasma protein medicament formulation would have been obvious given the claims of U.S. '318.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600